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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,099	10/31/2003	Dale B. Schenk	015270-008930US	7805

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,099	SCHENK ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/5/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 3/5/2007. The status of the claims is as follows: claims 1-6 and 9-13 are under current examination and claims 7-8 and 14-53 are canceled.

Claim Rejections

35 U.S.C. 103(a)-MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshimoto et al (1995) or Wakabayashi et al (1997), in further view of Que et al. (1998) and Cleland et al. (1995). Applicant's arguments were considered but not found persuasive. Briefly, these claims were previously rejected because the prior art by Yoshimoto et al disclosed a method of in which fragments of NACP, including a fragment which corresponds to NAC residues, were used for the preparation of affinity-purified rabbit anti-NACP polyclonal antibody (see Materials and Methods). Wakabayashi et al teach making an anti-NACP antibody that was raised by immunizing rabbits with recombinant NACP (see page 46). Both of these references disclose antibodies that bind to alpha-synuclein. Applicant does not traverse the teachings and state that they "effectively provide the same discussion of using alpha

synuclein to generate polyclonal antibodies" (page 4, Remarks). Applicant does, however, point out that the protocols used by these references include the use of Freund's adjuvant and provides literature teaching that "Freund's adjuvant is the most commonly used for immunization laboratory animals but is too toxic for use in humans" (page 5, Remarks). In response, Examiner would like to direct the Applicant attention to paragraph 232 of the instant specification reciting: "For example, Complete Freund's adjuvant is not suitable for human administration. Alum, MPL and QS-21 are preferred. Optionally, two or more different adjuvants can be used simultaneously. Preferred combinations include alum with MPL, alum with QS-21, MPL with QS-21, MPL or RC-529 with GM-CSF, and alum, QS-21 and MPL together. Also, Incomplete Freund's adjuvant can be used (Chang et al., Advanced Drug Delivery Reviews 32, 173-186 (1998)), optionally in combination with any of alum, QS-21, and MPL and all combinations thereof." Thus, the argument presented by the Applicant is incongruent with the teachings of the instant specification that suggests that Incomplete Freund's adjuvant can be used for human administration.

It is noted here that the previous claims filed 9/7/2004 were once upon a time drawn to a composition comprising Freund's adjuvant (see claim 8).

Separately, Applicant argues that there would be no motivation for one to *switch* from using Freund's adjuvant to QS21 and the skilled person would not be greatly concerned about the long shelf-life of an adjuvant for the following reasons: 1. the differential degradation characteristics of Freund's adjuvant in contrast to that of QS21 are not known; 2. the needs of stability are different in an HIV vaccine and laboratory

immunogen; and 3. it would require "little trouble for a technician to freshly mix adjuvant with immunogen on each such occasion" (see Remarks, page 6).

In response, there appears to be multiple shifts in the argument regarding what the related issues are. The Examiner never suggested that one would be motivated to *switch* from Freund's adjuvant to QS21. In fact, the Examiner never mentions Freund's adjuvant in the office action and a stability comparison between the adjuvants is not considered relevant to the 103 rejection; this comparison will not be discussed further. The applied motivation was that QS21 is a stable adjuvant contributing to its shelf life. Secondly, Applicant states "the needs of stability are different in an HIV vaccine and laboratory immunogen" (see Remarks, page 5). While this may be either true or false, this is not related to the rejection applied under 103. The issue is that Cleland et al disclose the kinetic analysis of QS21 degradation and determined the optimal conditions for stabilizing *QS21 itself* in aqueous solution (see Conclusions) and not of an HIV vaccine. Lastly, Applicant suggests that a technician could freshly mix adjuvant with immunogen as needed with little trouble. The little trouble required for an arbitrary technician in freshly mixing a composition is not relevant to the 103 rejection and will not be further discussed here. The motivation, to use a stable adjuvant well-characterized by the prior art, remains and has yet to be argued. Further, the instant specification provides no gain of function or unexpected results in combining the immunogen with the QS21 adjuvant. These claims remain rejected.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michelle Horning
Patent Examiner

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